Reduced Incidence of Revision Anterior Cruciate Ligament Reconstruction With Internal Brace Augmentation

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Background: Revision rates and outcome measures after anterior cruciate ligament reconstruction (ACLR) with suture tape as an internal brace is not well-documented because of the emerging nature of the technique.

Hypothesis: ACLR with internal bracing (IB) would lead to decreased revision ACLR compared with traditional ACLR while exhibiting comparable patient outcomes.

Study Design: Cohort study; Level of evidence, 3.

Methods: A total of 200 patients were included in this study. Patients aged between 13 and 39 years at the time of surgery who underwent primary autograft ACLR with IB between 2010 and 2020 and were enrolled in our institution's registry with a minimum of 2-year follow-up were identified and matched 1 to 1 with a non-internal brace (no-IB) group based on concomitant procedures and patient characteristics. Pre- and postoperatively, patients completed the Knee injury and Osteoarthritis Outcome Score, Marx activity rating scale, Veterans RAND 12-Item Health Survey, and visual analog scale for pain. Knee laxity measurements via the KT-1000 arthrometer were included in the pre- and postoperative objective clinical assessments.

Results: A total of 100 IB patients were matched with 100 no-IB patients based primarily on concomitant procedures and secondarily on patient characteristics. The IB group underwent significantly fewer revision ACLRs (1% vs 8%; $P = .017$). Even though the no-IB group had a significantly longer mean final follow-up time (48.6 months [95% CI, 45.4-51.7] vs 33.4 months [95% CI, 30.3-36.5]; $P < .001$), the time elapsed from the original ACLR to the revision did not differ significantly between groups, and the mean ages for the IB and no-IB groups were comparable (19 vs 19.9 years). All postoperative patient-reported outcome scores between the 2 groups were comparable and significantly improved postoperatively except for the Marx score, which significantly decreased stepwise for both groups postoperatively. KT-1000 measurements significantly improved in both groups after surgery with the IB and no-IB cohorts yielding comparable results at the manual maximum pull (0.97 vs 0.65 mm).

Conclusion: ACLR with IB resulted in a significantly decreased risk of revision ACLRs while maintaining comparable patient-reported outcomes. Therefore, incorporating an internal brace into ACLR appears to be safe and effective within these study parameters.

Keywords: anterior cruciate ligament; anterior cruciate ligament reconstruction; internal bracing; suture tape augmentation

Tears of the anterior cruciate ligament (ACL) are common athletic injuries that lead to anterior as well as rotational knee instability.[10,46] Approximately 100,000 to 200,000 ACL reconstructions (ACLRs) are annually performed in the United States.[15,29,41] ACLR is performed using various techniques and graft choices based on the surgeon's preference developed from clinical experience, patient expectations, and scientific evidence.[8,9,16,24] However, despite the variations in techniques and graft choices, the rate of a second ACL injury ranges from 6% to as high as 31% in the younger, more active population.[35]

Because of these high revision rates, suture tape augmentation—also referred to as internal bracing (IB)—has been proposed and implemented as an intervention to potentially decrease ACL graft failure.[1,23,42,48] Because of the novelty of the technique, there is limited clinical literature comparing ACLR with and without IB.[7,20,34] However, there have been numerous studies detailing the technique,[1,23,42,48,52] efficacy,[7,20,23,34] and safety,[7,20,23,34,47,49] along with mechanistic laboratory studies researching ACLR with IB.[2,3,17,23,50] In a scoping review including 6 biomechanical, 3 animal, 10 technical, and 3 clinical studies, Mackenzie et al[23] found that ACLR when augmented with suture tape as an internal brace significantly increased the strength of the graft complex and reduced graft elongation while maintaining equivalent complication rates as well as patient-reported outcomes (PROs) when compared with standard ACLR. Despite the promising results of previous studies that found IB to not only be safe[7,20,23,34,47] but also biomechanically superior to standard ACLR,[2,3,17,23,50,53] an

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unanswered question is whether ACLR with IB would translate clinically and lead to less graft retears or impact clinical outcomes and PROs.

Historically, there has been a negative connotation surrounding graft augmentations such as the Kennedy ligament augmentation device (braided polypropylene), which led to increased incidences of intra-articular synovitis, effusions, and infections.[5,21] In comparison, the present-day augmentation consists of a smaller suture tape that is composed of long-chain polyethylene, which has been proven to be biocompatible, thus decreasing the risk of the aforementioned complications associated with the Kennedy ligament augmentation device.[47]

The primary purpose of this study was to investigate retear rates in patients who underwent ACLR with and without IB in a matched case-control study. Additionally, we also sought to investigate whether there were any differences in clinical outcomes and PRO scores between the groups. We hypothesized that ACLR with IB would reduce the incidence of revisions safely and effectively.

METHODS

Study Design

This was a retrospective registry review study comparing 2 groups who underwent ACLR—those with IB (IB group) and those without IB (no-IB group). Each patient in the IB group was matched 1 to 1 with a patient in the no-IB group based on demographic characteristics (age at the time of surgery, sex, and body mass index [BMI]) as well as concomitant procedures (meniscus procedures, anterolateral ligament reconstruction, chondral lesions, etc). Because of the promising biomechanical properties of ACLR with suture tape augmentation, the senior surgeon (P.A.S.) implemented the internal brace technique in July 2016. The majority of ACLR procedures after this date were augmented with an internal brace; thus, there was not a single patient in the IB group who had undergone ACLR before July 2016.

Patient Eligibility

Patients were included if they had undergone primary autograft ACLR by the senior surgeon (P.A.S.), were enrolled in our institutional review board–approved registry (Surgical Outcomes System [SOS]) between 2010 and 2020, were between the ages of 13 to 39 years and skeletally mature at the time of the procedure, and had at least 2 years of postoperative follow-up. Skeletal maturity was determined by preoperative hand radiographs for all adolescent patients. Patients were excluded if they underwent revision ACLR without a history of primary ACLR performed at this institution by the senior surgeon within the stated timeline. Patients were also excluded if they underwent primary ACLR but were not enrolled in the SOS registry, underwent allograft ACLR, had an inadequate patient-reported follow-up, or were unable to be matched secondary to noncomparable concurrent procedures such as extra-articular stabilization or additional ligamentous procedures. The protocol for this study received institutional review board approval, and all patients enrolled in the SOS registry provided written informed consent.

A total of 424 patients were initially identified. After stratification using the inclusion criteria, a total of 288 potential patients were eligible, of whom 123 received primary ACLR with internal brace augmentation. Of these 123 patients, 100 were selected (IB group) and matched 1 to 1 against a no-IB group based on characteristics and concomitant procedures (Figure 1).

Data Collection

First, the registry was queried to identify those with appropriate follow-up and age at the time of surgery, excluding those who did not meet the criteria. Other demographic information—such as sex, laterality, and BMI—were also obtained from the registry. The patients completed the following validated PRO measures preoperatively via the registry: Knee injury and Osteoarthritis Outcome Score (KOOS)[40]; Marx activity rating scale[27]; Veterans RAND 12-Item Health Survey (VR-12)[45]; and visual analog scale (VAS) for pain.[37] Patients completed these measures again at 3 months, 6 months, 1 year, 2 years, and 5 years postoperatively.

Once patients were selected, paper-based operative diagrams were then searched to gather surgical information such as additional pathology/procedures, graft type, and graft size. Those with inappropriate graft types such as allografts, double-bundle reconstructions, or those with revision ACLRs were filtered out at this point, as such information was not readily available via the registry. Patients in the IB and no-IB groups were then matched primarily by concurrent procedures; thus, those who received extra-articular stabilization and meniscal procedures were matched with similar patients so as not to

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Ethical approval for this study was obtained from Salus IRB (ref No. SOS #1).

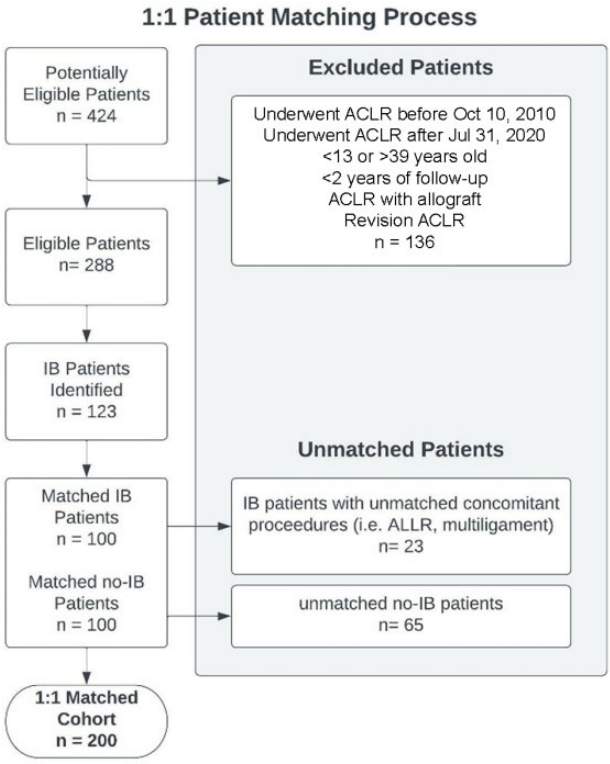

Figure 1. Flowchart of included and excluded patients and the matching process. ACLR, anterior cruciate ligament reconstruction; IB, internal brace.

obscure the final results. Patients were matched secondarily based on age at the time of surgery, sex, and BMI. Although initially attempted, it was not possible to match based on graft type; therefore, given more shared similarities with each other, patients with quadriceps tendon (QT) grafts were then matched with patients with bone–patellar tendon–bone (BTB) grafts as the senior surgeon transitioned to using more QT autografts than BTB autografts because of the concern of anterior knee discomfort. Of note, all available patients who received hamstring tendon (HT) grafts in the IB group were included in the final analysis. Once all patients were matched, the remaining IB patients (QTs ± anterolateral ligament reconstruction ± lateral collateral ligament/medial collateral ligament/posterior cruciate ligament procedures) were excluded. Conversely, all remaining patients in the no-IB group (isolated HT and BTB ACLR) were excluded so as to not further increase the heterogeneous gap between groups regarding graft type.

After matching was complete, the patient's electronic medical records were queried to retrieve the remaining information such as 1-year clinical outcome data, including knee motion and anteroposterior laxity measured via the KT-1000 arthrometer (MEDmetric). The KT-1000 arthrometer testing was performed by qualified research personnel who were blinded to the relevant radiological studies and the senior surgeon's physical examination. Additionally, the electronic medical records were used to obtain the need for subsequent procedures for the ipsilateral knee. Furthermore, a currently ongoing study regarding patient outcomes after ACLR with IB further reinforced the outcomes for the IB group but not the no-IB group.

Graft Preparation With Internal Brace Augmentation and ACLR

The surgical techniques were identical between groups, with the only difference being the additional internal brace augmentation in the IB group. The grafts used were all–soft tissue QT autografts, BTB autografts, or quadrupled GraftLink semitendinosus HT autografts. The QT and HT grafts were prepared similarly for all-inside ACLR, attaching a suspensory adjustable-loop device (ALD) (ACL TightRope RT; Arthrex) on both sides of the graft for socket fixation.[42,50] For the internal brace (InternalBrace; Arthrex), a 2 mm–wide and 0.5 mm–thick suture tape (FiberTape; Arthrex) was passed through the ALD femoral button to be separate and independent from the graft passed through the loop of the ALD (Figure 2). The BTB grafts were prepared with an ALD through the femoral bone plug for femoral fixation, with the internal brace attached to the button similar to the QT and HT autografts.

The femoral socket was created independently from the tibia via anteromedial portal reaming with the all-inside tibial socket (QT and HT grafts) or full tibial tunnel (BTB grafts) created with retroreaming from the joint line. After passage and initial femoral fixation, in all cases, the internal brace was always fixed before final tibial ACL graft fixation to ensure the independence of the graft fixation to the internal brace. This was achieved by passing the 2 free ends of the suture tape through the tibial fixation button of the suspensory fixation device for the QT and HT grafts and fixing the internal brace to the tibia distal to the button utilizing an absorbable 4.5 mm anchor (BioComposite SwiveLock; Arthrex).[42,50] Internal brace fixation was always performed while holding the foot so the knee was fully hyperextended. Then, the tibial shortening strands were pulled to dock the graft in the tibial socket. For BTB grafts, a complete tibial tunnel was made with internal brace fixation performed first with the same tibial anchor with the knee in full hyperextension, followed by tibial graft fixation with an absorbable interference screw (BioComposite Interference Screw; Arthrex). The knees were cycled through a full range of motion (ROM) several times, with re-tensioning of the ALDs done both on the femoral and tibial sides for the QT and HT grafts in full hyperextension. For the BTB grafts, retensioning could only be done on the femoral side with the ALD again in full knee hyperextension.

Any concurrent intra-articular pathologies were addressed before ACLR. Indicated extra-articular stabilization was performed after ACLR if the patients were young, demonstrated knee hyperextension, and participated in high-risk pivoting sports. An example of a reconstructed ACL with the internal brace technique is shown in Figure 3.

To further reiterate, the only additional implants used for the IB group were the suture tape, which served as the internal brace as well as the bioabsorbable suture anchor

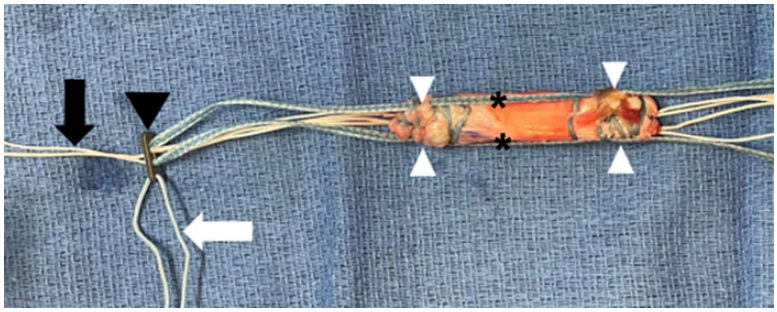

Figure 2. An intraoperative photograph of an all–soft tissue quadriceps tendon autograft prepared for both proximal and distal suspensory fixation with additional independent internal brace augmentation. The pull suture (white arrow) is used to pass the femoral cortical button (black arrowhead) through the femoral socket. The femoral shortening strands (black arrow) are used for docking the graft into the socket and retensioning the graft proximally to achieve final graft fixation. The internal brace is passed through 2 holes on the femoral button where it then runs parallel to the graft (asterisks). A nitinol wire (not pictured) is used to pass the internal brace under 1 suture on the graft both proximally and distally on both sides (white arrowheads).

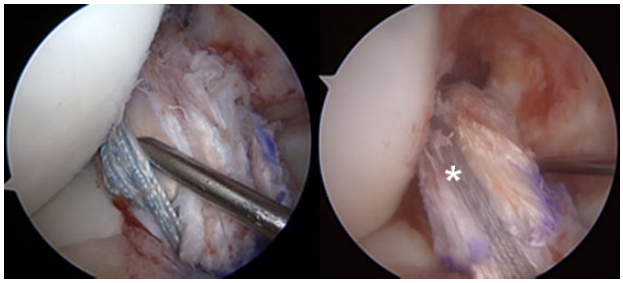

Figure 3. Intraoperative arthroscopic views of a right knee from the anterolateral portal of 2 quadriceps tendon autografts at 60° of flexion with internal brace augmentation (asterisk).

that was used for tibial fixation. The remaining techniques and implants used were the same for both groups.

Postoperative Rehabilitation

The postoperative rehabilitation program was the same in both groups. A continuous passive motion machine (Kinex-CONNECT; Kinex Medical) was utilized for the first 2 weeks at home to facilitate the return of motion. Supervised physical therapy was instituted on postoperative day 2 focusing on quadriceps exercises for full extension. Full weightbearing was allowed once the patient had adequate quadriceps strength and good leg control, usually by 2 weeks, although dependent in some cases on specific meniscal repair procedures performed. Closed-chain exercises were initiated once the patient was fully weightbearing. Jogging was generally allowed at 3 months postoperatively, with agility exercises at 4 months and sport-specific exercises at 5 months. Minimal clearance to return to sports was 6 months depending on physician evaluation, passage of return to play functional testing, and overall patient confidence.

Patients were seen in the clinic for follow-ups at 2 weeks, 10 weeks, and 6 months postoperatively. Once cleared to return to sports, they were instructed to schedule future appointments as needed, although they were scheduled to return to the office for a 1-year follow-up for a final assessment consisting of a physical examination and KT-1000 arthrometer measurement. Additionally, all patients were encouraged to complete their postoperative PRO measures.

Statistical Analysis

Continuous variables were reported as means with 95% confidence intervals or medians with interquartile ranges (IQRs). Comparisons between continuous variables were performed using either the Student t test or the Mann-Whitney U test. Categorical variables were reported as absolute values, and comparisons between categorical variables were performed using either the chi-square test or the Fisher exact test. Data analyses were performed using JMP Version 17 (SAS Institute). A Kaplan-Meier survival curve was estimated based on the available data, and a pairwise comparison was performed using the log-rank test using OriginPro 2020b (Version 9.7.5.184; OriginLab). A $P < .05$ was considered statistically significant for all comparisons.

RESULTS

Patient Characteristics

The characteristics of the 200 study patients are summarized in Table 1. Both groups were statistically comparable for their shared characteristics with only 2 exceptions. The no-IB group had a significantly longer mean final follow-up (48.6 months [95% CI, 45.4-51.7] vs 33.4 months [95% CI, 30.3-36.5]; $P < .001$). Also, the autograft types in both groups were significantly different ($P < .001$), as there were significantly more QT autografts used in the IB group (51 vs 26; $P < .001$) and significantly more BTB autografts used in the no-IB group (46 vs 23; $P = .003$). The HT autografts used were comparable between groups.

TABLE 1
Patient Characteristics[a]

Parameter	IB (n = 100)	No-IB (n = 100)	*P*
Age at surgery, y	19 (17.9-20.1)	19.9 (18.8-21)	.236
Sex			>.999
Male	49	49	
Female	51	51	
BMI, kg/m^2	25.5 (24.2-26.9)	26.1 (25.0-27.2)	.101
Laterality			.888
Left	50	51	
Right	50	49	
Graft type			**<.001**
HT	26	28	
QT	51	26	
BTB	23	46	
Graft diameter/width, mm			
HT	8.92 (8.69-9.16)	8.88 (8.60-9.16)	.807
QT	10.5 (10.3-10.6)	10.4 (10.1-10.7)	.876
BTB	11.2 (10.8-11.7)	11.2 (10.9-11.6)	.956
Final follow-up, mo	33.4 (30.3-36.5)	48.6 (45.4-51.7)	**<.001**
Concomitant procedures[b]	84	89	.729
Meniscal procedures	64	69	
Partial meniscectomy	17	18	
Meniscal repair	42	45	
Meniscal root repair	4	5	
Meniscal abrasion	1	1	
Chondroplasty	6	6	
ALLR	13	13	
MCL repair	1	1	

[a]Data are presented as mean (95% confidence interval) or No. of patients. Bold *P* values indicate statistically significant differences between groups ($P < .05$). ALLR, anterolateral ligament reconstruction; BMI, body mass index; BTB, bone–patellar-tendon–bone; HT, quadrupled semitendinosus hamstring tendon; IB, internal brace; MCL, medial collateral ligament; QT, quadriceps tendon.
[b]A single patient could have received more than 1 concomitant procedure.

Reoperations

The subsequent procedures that occurred concomitantly with revision ACLRs are summarized in Table 2. Compared with the IB group, the no-IB group underwent significantly more revision ACLRs (8 vs 1; $P = .017$), meniscal procedures (9 vs 1; $P = .009$), and anterolateral ligament reconstructions (ALLRs) (0 vs 4; $P = .043$). The time from primary to revision ACLR for the single patient in the IB group was 21 months, and the median time from the primary to revision ACLR for the 8 patients in the no-IB group was 18 months (IQR, 15.3-35.3 months). Five patients in the no-IB group underwent a partial meniscectomy, meniscal repair, or a combination of the 2 at the time of their revision, accounting for a total of 9 total meniscal procedures performed in these patients. Only 1 patient in the no-IB group underwent isolated revision ACLR. Of note, there were not any patients in either group who demonstrated clinical failures that were treated nonoperatively. When controlling for revision ACLRs, there were no significant differences in the IB and no-IB groups for subsequent non-ACL reoperations or procedures done (Table 3).

TABLE 2
Subsequent Procedures Occurred Concomitantly With Revision ACLR[a]

Procedure[b]	IB (n = 100)	No-IB (n = 100)	*P*
Total revision ACLR	1	8	**.017**
Total meniscal procedures	1	9	**.009**
Partial meniscectomy	0	3	.081
Meniscal repair	1	5	.097
Meniscal root repair	0	1	.32
ALLR	0	4	**.043**
Chondroplasty	0	1	.32
FPF excision	0	1	.32
Loose body removal	0	1	.32
Hardware removal	1	1	>.999
Time from ACLR to revision, mo	21 mo (n = 1 patient)	25 (12-38)	.85

[a]Data are presented as No. of patients or mean (95% confidence interval) unless otherwise indicated. Bold *P* values indicate statistically significant differences between groups ($P < .05$). ACLR, anterior cruciate ligament reconstruction; ALLR, anterolateral ligament reconstruction; FPF, fat pad fibrosis; IB, internal brace.
[b]A single patient may have undergone more than 1 procedure.

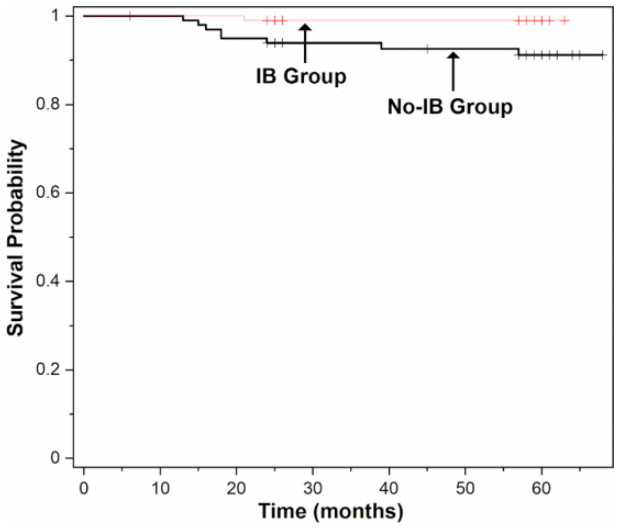

Figure 4. Kaplan-Meier survival curve for the available time frame. Censored data are denoted by a plus (+) symbol.

A Kaplan-Meier survival curve demonstrated statistically significant differences based on the log-rank test pairwise comparison with a cumulative survival of 0.99 (0.01 SE) for the IB group and 0.91 (0.03 SE) for the no-IB group, respectively (Figure 4). The ACL revision events occurred after 13 months.

Subjective and Objective Patient Outcomes

The preoperative PRO scores were comparable between the groups (Table 4) with near identical mean preinjury

TABLE 3
Subsequent Procedures That Did Not Involve Concomitant ACLR[a]

Procedure	IB (n = 99)	No-IB (n = 92)	*P*
Total non-ACL reoperations[b]	17	16	.97
Meniscal procedures	6	7	.67
Partial meniscectomy	6	5	
Meniscal repair	0	2	
Chondroplasty	1	2	.52
Debriding procedures[c]	11	9	.76
Loose body removal	0	1	.30
Hardware removal	1	2	.52
Subsequent contralateral ACLR	6	7	.67

[a]Data are presented as No. of patients. ACLR, anterior cruciate ligament reconstruction; IB, internal brace.
[b]A single reoperation may consist of more than 1 procedure.
[c]Synovectomies and anterior scar tissue debridement.

TABLE 4
Patient-Reported Outcomes Preoperatively[α]

Outcome Measure	IB (n = 100)	No-IB (n = 100)	*P*
VAS pain	2.55 (2.15-2.95)	2.27 (1.85-2.69)	.205
Marx[b]	13.4 (12.6-14.2)	13.4 (12.6-14.3)	.781
KOOS			
Pain	66.4 (63-69.7)	65.3 (62.1-68.5)	.469
Symptoms	56.7 (53.1-60.2)	59.2 (55.9-62.5)	.330
ADL	74.3 (70.9-77.7)	73.7 (70.3-77.1)	.809
Sports/Rec	28.8 (22.9-34.6)	31.2 (25.7-36.6)	.443
QoL	31.8 (27.6-35.9)	32.7 (28.7-36.6)	.747
VR-12			
Physical	37.9 (36.1-39.8)	37.5 (36-39.1)	.682
Mental	52.8 (50.9-54.8)	52.6 (50.4-54.8)	.897

[α]Data are presented as mean (95% confidence interval). ADL, activities of daily living; IB, internal brace; KOOS, Knee injury, and Osteoarthritis Outcome Score; QoL, quality of life; Rec, recreation; VAS, visual analog scale; VR-12, Veterans RAND 12-item health survey.
[b]Representative of preinjury activity levels.

activity levels (13.4 [95% CI, 12.6-14.2] vs 13.4 [95% CI, 12.6-14.3]; $P = .781$).

The 2- and 5-year postoperative PRO scores are summarized in Table 5. Both groups demonstrated comparable postoperative scores. The Marx scores significantly decreased in a stepwise manner compared with preinjury levels for both groups. Only 29% of the patients in the study were eligible to complete their 5-year patient-reported outcome measures (PROMs) compared with 74% of the patients in the control group. Except for the Marx score, all PROMs in the IB group significantly improved postoperatively at both time points. Additionally, no differences were observed between years 2 and 5.

For the no-IB group, the VAS, KOOS, and VR-12 Physical scores all improved postoperatively at both time points. Additionally, no differences were observed between the 2 time points regarding the aforementioned outcome measures. Regarding the mental component of the VR-12, there was a significant decrease from postoperative years 2 to 5 (56.7 [95% CI, 55.2-58.2] vs 53.6 [95% CI, 51.5-55.7]; $P = .0150$). Furthermore, no apparent change was found between preoperative and 5-year scores regarding this outcome (52.6 [95% CI, 50.4-54.8] vs 53.6 [95% CI, 51.5-55.7]; $P = .790$).

In terms of clinical evaluation, there were no significant differences between the groups pre- or postoperatively regarding ROM and objective laxity measurements. Clinical outcomes relative to knee motion and anteroposterior laxity improved significantly after the procedure for both groups. The details are summarized in Table 6. Of note, the IB group had a shorter follow-up time of 15 months compared with the no-IB group (see Table 1).

DISCUSSION

The most important finding of this study was that ACLRs with IB reduced the incidence of ACL revision by 88% (1% vs 8%; $P = .017$). The theory for this improvement stems from the prior mechanistic research demonstrating improved mechanical properties and shared loading to protect the graft from unforeseen high loads during the remodeling phase, as well as later on with return to sports activities.[2,3,17,23,50,53] Considering that the revision ACLR range in the literature varies[35] from as low as 6% to as high as 31%, the need for revision ACLR in our IB group was 1%, which is quite impactful. Our study showed that ACLR with IB might be a solution to decrease the need for revision ACLR, especially in the younger, more active demographic group who are at an increased risk for graft retears.[32,35,52] The mean patient age in our study was 19 years because we wanted to include the population that would most likely experience ACL graft failure requiring revision surgery.[32,35,52] Although the retear rate of 8% in our no-IB group would be acceptable based on the literature of patients with similar ages, reducing that to 1% by adding an internal brace is extremely valuable clinically,[26] economically,[38] and for the patient's overall mental and physical well-being.[51] It is well known that revision ACLRs do not do as well as primary procedures,[11,22,25] and thus a major goal with ACLR should be to avoid graft retears.

There was a significant difference in the grafts utilized between groups because of changes in the senior surgeon's graft preferences over the years. In the earlier patients (2010-2016), the main graft choice was the BTB autograft, the historic gold standard.[13,50] Because of the concern of BTB autografts resulting in more anterior knee pain after ACLR,[12,31,44] the senior surgeon transitioned from less BTB autografts to more QT autografts instead (2016-present). Despite this use of more QT than BTB grafts for the IB group, studies have shown equivalent outcomes with retear rates between BTB and QT autografts.[25,36,54]

On further graft analysis in this study, there were no significant differences in the diameters of the HT and QT grafts, nor differences between the widths of the BTB grafts in the groups. Also, there were no significant differences between the 8 grafts that tore in the no-IB group, as 5 were HT autografts and 3 were BTB autografts. Regarding the

TABLE 5
Patient-Reported Outcomes at 2 and 5 Years Postoperatively[a]

	2 Years Postoperatively			5 Years Postoperatively		
Outcome Measure	IB (n = 100)	No-IB (n = 100)	*P*	IB (n = 29)	No-IB (n = 74)	*P*
VAS pain[b]	0.557 (0.364-0.751)	0.769 (0.149-0.474)	.401	0.874 (0.257-1.49)	0.803 (0.459-1.15)	.658
Marx[c,d]	11.2 (10.2-12.1)	10.4 (9.42-11.5)	.326	7.93 (6.22-9.64)	7.24 (6.14-8.34)	.493
KOOS[b]						
Pain	91.5 (89.6-93.3)	91.3 (89.1-93.5)	.665	90.8 (86.3-95.4)	91.1 (88.5-93.7)	.646
Symptoms	82.6 (79.9-85.3)	83.9 (81.1-86.8)	.347	82.7 (77.4-88)	85.5 (82.5-88.5)	.294
ADL	96.6 (95.4-97.9)	96.1 (94.2-98)	.707	95.7 (92.8-98.6)	95.7 (93.8-97.5)	.952
Sports/Rec	85.2 (81.7-88.7)	84.1 (80.1-88.1)	.857	78.2 (67.8-88.6)	81.4 (75.5-87.3)	.577
QoL	79.4 (76.1-82.8)	77.8 (74-81.5)	.555	77.1 (68.8-85.4)	80.8 (76.2-85.4)	.363
VR-12						
Physical[b]	52.7 (51.6-53.8)	52.6 (51.4-53.8)	.966	51.4 (49.1-53.6)	52.9 (51.7-54.1)	.0842
Mental	56.2[b] (54.7-57.7)	56.7[β] (55.2-58.2)	.507	57.2[b] (55.2-59.1)	53.6[c,d] (51.5-55.7)	.119

[a]Data are presented as mean (95% confidence intervals). ADL, activities of daily living; IB, internal brace; KOOS, Knee Injury and Osteoarthritis Outcome Score; QoL, quality of life; Rec, recreation; VAS, visual analog scale; VR-12, Veterans RAND 12 Item Health Survey.
[b]Significantly improved postoperative outcomes compared with preoperative outcomes.
[c]Significantly lower 5-year outcomes compared with 2-year outcomes.
[d]Significantly lower postoperative outcomes compared with preoperative outcomes.

TABLE 6
Preoperative and Final Clinical Outcomes[α]

	Preoperative			Final Follow-up		
Outcome	IB	No-IB	P	IB	No-IB	*P*
AP knee laxity[b]	6.17 (5.83-6.51)[d]	6.04 (5.40- 6.69)[e]	.394	0.971 (0.738- 1.20)[f]	0.651 (0.401- 0.901)[g]	.0747
Extension, deg[b,c]	1.33 (0.265- 2.40)	1.72 (0.620- 2.81)	.665	–0.583 (–0.918 to –0.249)	–0.634 (–0.958 to –0.311)	.159
Flexion, deg[b]	117 (113-122)	115 (111- 120)	.562	139 (137-140)	138 (137-139)	.150

[α]Data are presented as mean (95% confidence interval). The group sample size was 100 patients unless otherwise indicated. AP, anteroposterior; IB, internal brace.
[b]Significant differences between preoperative and final follow-up values.
[c]Negative values represent hyperextension.
[d]n = 95.
[e]n = 48.
[f]n = 70.
[g]n = 43.

HT autografts, our mean diameter was approximately 8.9 mm in both groups. The mean diameter of the HT autografts that tore was 8.7 mm (95% CI, 7.7-9.6), which was comparable with those that remained intact.

IB did not over constrain the knee as evidenced by the KT-1000 arthrometer measurements. In addition, mean postoperative hyperextension was achieved in both groups, providing further evidence that the internal brace did not over constrain the joint or limit extension when the senior surgeon tensioned and fixed the internal brace while the knee was fully hyperextended.

The mean final follow-up time was over a year longer in the no-IB group compared with the IB group. This resulted in the inability to obtain 5-year PRO scores from 71% of the IB group. Since IB for ACLR was not introduced until recently,[47,48] a majority of those patients were just not eligible to complete their 5-year surveys. An additional difference between the groups was the increased incidence of subsequent meniscal damage that necessitated surgical intervention. This was because of the increased need for revision ACLR since these structures are commonly injured and surgically addressed concomitantly[15,19,39]; furthermore, when excluding revision ACLR cases, there was no significant difference between groups regarding subsequent surgical intervention for meniscal pathology. Protecting the meniscus is another critical point about the benefit of the internal brace decreasing graft retears, as in this study, 5% of the no-IB patients had a total of 9 meniscal procedures done at the time of their revision ACLR.

Regarding the postoperative PRO scores, the Marx scores decreased in a stepwise manner for both groups, although being compared with each other at their respective time points. Typically, in this patient population, activity levels tend to decrease the further away the patient is from their ACLR.[6,18,43] Of note, the no-IB group

demonstrated lower scores on the mental aspect of the VR-12 at the 5-year follow-up compared with their 2-year follow-up. Furthermore, their scores at 5 years were comparable with their preoperative scores. In our opinion, this is an incidental finding, as these lower scores were not correlated with increased pain levels or decreased overall function; furthermore, we do not believe that this is related to the absence of an internal brace.

Bodendorfer et al[7] found that augmenting ACLR with an internal brace correlated with improved PROs, higher return to preinjury levels, and faster return to sports compared with patients who underwent standard ACLR. Despite the promising results obtained by Bodendorfer et al, we were unable to reproduce similar findings. Additionally, the main focus of this study was not to assess the rate at which the patients returned to their sports or the level of competition to which they returned.

Additional ACL graft augmentation has been historically controversial because of the adverse intra-articular side effects experienced after augmentation with synthetic devices such as the Kennedy ligament augmentation device.[5,21] However, as similar as the concepts of the ligament augmentation device and the internal brace may be, there is a significant amount of supporting literature for the internal brace, demonstrating the safety and biocompatibility of the construct.[7,20,23,34,47,49] Furthermore, there has not been any published literature documenting the consequences of ACLR augmentation using long-chain polyethylene suture tapes.

Limitations

This study was not without limitations. First, the mean time to final follow-up was more than a year longer for the no-IB group compared with the IB group. Also, 74% of the patients in the no-IB group completed 5-year PRO measures compared with 29% in the IB group. Next, because of the nature of this study, there is a possibility of selection bias. We selected the non-IB group nonrandomly based on the IB group's concomitant procedures and characteristics. We did this because we did not want to match IB patients who underwent certain additional procedures to a no-IB cohort that did not undergo such procedures, as the remaining IB patients either underwent ALLR or were multiligamentous cases. The protective properties of the ACL graft with extra-articular stabilization are well-documented[14,28,33]; thus, naturally this was the variable we wanted to control the most, and after matching, each group contained 11 ALLRs. Additionally, multiligamentous cases have been shown to lead to lower subjective outcomes compared with isolated ACLR,[4,30] and we did not want to skew our results. Next, the window from which the patients were chosen was 10 years. Since the senior surgeon began implementing the IB technique in the mid-2016, almost every patient undergoing ACLR has received an internal brace. This may suggest that patients who underwent the procedure more recently were not only more likely to have received an internal brace but also may have benefitted from the senior surgeon's increasing surgical proficiency. However, from 2010 to mid-2020 alone, the senior surgeon performed well over 1000 ACLRs using the same techniques since 2006, which strongly suggests that increasing surgical proficiency did not play a major role. Furthermore, 85% of the patients in the no-IB group received ACLR from 2014 onwards. Even though the mean time from the primary ACLR to revision did not differ between the 2 groups, the final follow-up timeline discrepancy may have also allowed more time for patients in the no-IB group to sustain injuries to the ipsilateral leg, which may have led to more non-ACL procedures or decreased patient satisfaction. However, studies have shown that the majority of ACL graft retears occur within the first 2 years after their primary procedure,[32,35,52] which is also why we believe that this follow-up time discrepancy may not be a relevant limitation regarding subsequent revisions specifically. Another limitation may have been the nonuniformity of the grafts that were used. Even though recent studies have shown that ACL retear rates are comparable between the 3 types of autografts,[25,36] not comparing the grafts at a 1 to 1 to 1 ratio may have subjected the data to confounders that were unaccounted for. Even though we obtained clinical and subjective data, we did not include imaging, and thus we were unable to assess the progression of any arthritic changes that may have correlated with decreased patient outcomes or intra-articular pathologies that may have resulted from the internal brace itself. Because of only using retrospective registry data, we were unable to include patients outside of the registry, thus limiting the study's power. However, a single surgeon with established and consistent physical therapy protocols allows for a refined view of the impact of the internal brace technique.

CONCLUSION

ACLR with IB resulted in a significantly decreased risk of revision ACLRs while maintaining comparable PROs. Therefore, incorporating an internal brace into ACLR appears to be safe and effective within these study parameters.

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